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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,998	04/10/2000	Daniel M. Gorman	DX0612K1B	7858

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DNAX RESEARCH, INC.  
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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n N .

09/545,998

Applicant(s)

GORMAN ET AL.

Examin r

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/2003 has been entered.

2. Claims 6,23-29 are under consideration. Claims 6,29 have been amended. Claims 28-30 have been renumbered as 27-29 because no claim 27 was filed in the amendment filed 3/19/2002.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "peptide of at least 8 amino acids" in claim 29, section b). Regarding the specification, page 8 and 29, said passages do not disclose a kit with a "peptide of at least 8 amino acids" and the ingredients recited in said claim. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 6,26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Baum et al. (US Patent 5,457,035). Applicants arguments have been considered and deemed not persuasive.

Baum et al. teach monoclonal antibodies which bind OX40-L (see column 24). Said antibodies would bind any epitope on OX40-L. OX40-L has amino acid sequences in common with SEQ. ID. NO. 4 (for example amino acids 139-143 of OX40-L (columns 31-32) are found in SEQ. ID. NO. 4). The specification does not disclose what amino acid subsequences of SEQ. ID. NO. 4 actually constitute antibody epitopes. However, antibodies which bind amino acids 139-143 of OX40-L would bind the same sequence in SEQ. ID. NO. 4.

Regarding applicants comments, the specification, page 16, lines 28-37 actually does not define what "specifically binds a protein" means or encompasses. Lines 28-37 of the specification refer to antibodies that are "specifically immunoreactive with that particular protein *and not with other proteins*". Thus, the aforementioned two properties are not necessarily connected, and said phrase refers to "specifically immunoreactive", not "specifically binds". The specification, page 16, lines 28-30 disclose that "Specific binding to an antibody under such conditions may require an antibody that is selected for its specificity for a particular protein". Thus, the aforementioned two properties are not necessarily connected. Furthermore, the specification, page 16 lines 16-29 **actually defines "specifically binds to an antibody" as meaning that the antibody binds an epitope and that the epitope is found in a protein.** Said definition does not state that the epitope is only found in a protein/peptide of SEQ. ID. NO:2 or 4. Thus, the properties of "specific binding" and not reacting with other proteins are not necessarily connected. Applicants arguments involve limitations not currently recited in the claims under consideration. Regarding applicants comments, an antibody which bound the amino acids 139-143 of OX40-L would bind the same sequence in intact SEQ. ID. NO. 4. It is also noted that the current claim specifies the length of the peptide bound, not the length of the epitope bound by the antibody.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 23-2<sup>8</sup>~~9~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 5,457,035) in view of Godowski et al. (US Patent 5709858). Applicants arguments have been considered and deemed not persuasive.


Baum et al. teach monoclonal antibodies which bind OX40-L (see column 24). Said antibodies would bind any epitope on OX40-L. OX40-L has amino acid sequences in common with SEQ. ID. NO. 4 (for example amino acids 139-143 of OX40-L (columns 31-32) are found in SEQ. ID. NO. 4). The specification does not disclose what amino acid subsequences of SEQ. ID. NO. 4 actually constitute antibody epitopes. However, antibodies which bind amino acids 139-143 of OX40-L would bind the same sequence in SEQ. ID. NO. 4. Baum et al. do not teach the claimed antibody composition, antibody fragments or antibodies of claims 24, 25, 29. Godowski et al. teach antibody fragments, humanized antibodies, labeled antibodies and immobilized antibodies wherein said molecules are produced using art known methods and wherein said reagents have well known uses (see columns 36-39). Said molecules would have been produced based on any known antibody. The antibodies would have been prepared in a composition containing buffer for use in a variety of art known methods (immunoassays, affinity purification, etc). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Baum et al. teach monoclonal antibodies which bind SEQ. ID. NO. 4 and Godowski et al. teach antibody fragments, humanized antibodies, labeled antibodies and immobilized antibodies wherein said molecules are produced using art known methods and wherein said reagents have well known uses.

Applicants arguments are the same as addressed in paragraph <sup>6</sup>~~8~~ of this Office Action.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644

  
RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600-1644